



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,561	06/06/2007	Kazuhiro Abe	H-KN-00175 (TYCK 0175.14)	7239
54964 7590 12/29/2008 TYCO HEALTHCARE - EDWARD S. JARMOLOWICZ 15 HAMPSHIRE STREET MANSFIELD, MA 02048			EXAMINER DANG, PHONG SON H	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 12/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,561	Applicant(s) ABE ET AL.	
	Examiner SON DANG	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7-15 is/are rejected.
- 7) ☒ Claim(s) 4-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/06/2006, 02/23/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “positioning member” in claim 13 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 7-13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,638,286 to Burbank et al. (Burbank).

In Reference to Claim 1:

Burbank teaches:

A medical suturing tool comprising: an insertion puncture needle (120, Fig. 1) formed with an insertion hole (142, Fig. 3) from the proximal end to the distal end; a retrieval puncture needle (122, Fig. 1) disposed substantially in parallel with the insertion puncture needle (120, Fig. 1) at a predetermined distance therefrom; and a surgical suture (124, Fig. 1) extending from the proximal end of the insertion puncture needle (120, Fig. 1) through the distal end and then engaged with the distal end of the retrieval puncture needle (122, Fig. 1) via an engaging portion (134, Fig. 7).

In Reference to Claim 2:

Burbank teaches:

A tool according to claim 1 (see rejection of Claim 1 above), comprising:
an elongate opening (125, Fig. 7) provided on a surface of the insertion puncture needle (120, Fig. 7) opposing to the retrieval puncture needle (122, Fig. 7) in communication with the insertion hole; an engaging member (134, Fig. 7) being capable of moving in the insertion hole of the insertion puncture needle (120, Fig. 7) and, when having reached a predetermined position in the insertion hole, bending from the side of the upper end portion thereof to project outside from the elongate opening (125, Fig. 7); and an engaging groove (127, Fig. 7) provided on a surface of the retrieval puncture needle (122, Fig. 7) opposing to the insertion puncture needle (120, Fig. 7), wherein the surgical suture (124, Fig. 7) is connected to the lower end of the engaging member (134, Fig. 7) so that the suturing tool engages with the engaging groove on the retrieval puncture needle (122, Fig. 7) after having passed from the proximal end to the distal end of the insertion puncture needle (120, Fig. 7) together with the engaging member (134, Fig. 7).

In Reference to Claim 3:

Burbank teaches:

A tool according to claim 2 (see rejection of Claim 2 above), wherein the engaging groove (127, Fig. 7) includes a storage recess (144, Fig. 7) capable of accommodating the engaging member (134, Fig. 7) and an engaged portion (127, Fig. 7) with which the upper end portion of the engaging member can engage.

Art Unit: 3773

In Reference to Claim 7:

Burbank teaches:

A tool according to claim 2 (see rejection of Claim 2 above), in which the portion on the distal side of the insertion puncture needle (120, Fig. 7) with respect to the elongate opening (125, Fig. 7) and at least part of the retrieval puncture needle (122, Fig. 7) other than the portion where the engaging groove (127, Fig. 7) is formed is formed as a solid portion.

In Reference to Claim 8:

Burbank teaches:

A tool according to claim 2 (see rejection of Claim 2 above), wherein at least a portion of the insertion puncture needle (120, Fig. 7) where the elongate opening (125, Fig. 7) is formed and of at least a portion of the retrieval puncture needle (122, Fig. 7) where the engaging groove (127, Fig. 7) is formed are formed into an angular C-shape in lateral cross section Fig. 7), respectively, and are arranged so that the open sides are opposed to each other (Fig. 7).

In Reference to Claim 9:

Burbank teaches:

A tool according to claim 1 (see rejection of Claim 1 above), wherein needle points of the insertion puncture needle and the retrieval puncture needle (120, 122, Fig. 7) are formed into a pointed conical shape or a tapered thin blade shape (Fig. 7).

In Reference to Claim 10:

Art Unit: 3773

Burbank teaches:

A tool according to claim 1 (see rejection of Claim 1 above), wherein at least one of the insertion puncture needle and the retrieval puncture needle (120, 122, Fig. 7) is formed by connecting a metal member and a resin member (Claims 10 recites limitations based on process steps, this is being interpreted as a product-by-process limitations, as such only the structure implied by the steps is limited. See MPEP 2113. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15).

In Reference to Claim 11:

Burbank teaches:

A tool according to claim 1 (see rejection of Claim 1 above), wherein the insertion puncture needle and the retrieval puncture needle (120, 122, Fig. 1) are releasably attached to a retaining member (104, Fig.1).

In Reference to Claim 12:

Burbank teaches:

A tool according to claim 11 (see rejection of Claim 11 above), wherein the retaining member (104, Fig. 7) is constituted of a grip member to be held by a hand.

In Reference to Claim 13:

Burbank teaches:

A tool according to claim 11 (see rejection of Claim 11 above), further including a positioning member (112, 114, Fig. 2) for regulating the mounting positions of the insertion puncture needle and the retrieval puncture needle (120, 122, Fig. 2) with respect to the retaining member (104, Fig. 2).

In Reference to Claim 15:

Burbank teaches:

A medical suturing tool comprising an insertion puncture needle (120, Fig. 1) with a shaft having a proximal end and a pointed distal end, and a retrieval puncture needle (122, Fig. 1) with a shaft having a proximal end and a pointed distal end, and a retaining member (104, Fig. 1) that connects the respective proximal ends to retain the respective shafts parallel, wherein the insertion needle shaft (120, Fig. 7) having an elongate aperture (125, Fig. 7) in its wall surface facing the retrieval needle shaft (122, Fig. 7), the retrieval needle shaft (122, Fig. 7) having an aperture in its wall (127, Fig. 7) surface facing the insertion needle shaft (120, Fig. 7), the respective shafts each defining a lumen (142, 144, Fig. 3) from the proximal end to the respective aperture, and the insertion needle lumen (142, Fig. 3) containing an elongate lock part (134, Fig. 7)

Art Unit: 3773

long enough to bridge across from the insertion needle aperture (125, Fig. 7) to the retrieval needle aperture (127, Fig. 7) the insertion needle lumen (142, Fig. 3) containing a suture (124, Fig. 7) which is attached to the lock part (134, Fig. 7) whereby pulling on the suture causes the lock part to emerge from the insertion needle lumen (125, Fig. 7) and extend across to the retrieval needle aperture (127, Fig. 7) so that, withdrawal of the retrieval needle (122, Fig. 7), the suture (124, Fig. 7) is advanced from the puncture made by the insertion needle (120, Fig. 7) to the puncture made by the retrieval needle (122, Fig. 7).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank.

In Reference to Claim 14:

Burbank teaches:

A tool according to claim 11 (see rejection of Claim 11 above), wherein a plurality of pairs of the insertion puncture needle and the retrieval puncture needle are provided on the retaining member. (It would have been obvious to one of ordinary skill in the art at the time of the invention to use more than one

Art Unit: 3773

pair of needle to for faster suturing or for doing multiple stitching at the same time to save time. MPEP 2144.0 [R-6]).

Allowable Subject Matter

5. Claims 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 5,037,433 to Wilk et al. teaches an endoscopic suturing device and related method and suture.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809. The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SD

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773